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Original Article

Effects of a falls exercise intervention on strength, power, functional ability and bone in older frequent fallers: FaME (Falls Management Exercise) RCT secondary analysis

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Abstract

Objectives: Falls Management Exercise (FaME) has been shown to reduce falls in frequent fallers and in lower risk sedentary older people. The effects of FaME on the strength, power, physical function and bone health of frequently falling older women are yet to be established. **Methods:** This paper reports secondary analysis of data from the original randomised controlled trial of FaME in 100 community dwelling women aged ≥ 65 years with a history of ≥ 3 falls in the previous year. Intervention was group delivered, weekly one hour tailored dynamic balance and strength exercise classes and home exercise for nine months. Outcome measures included: strength (handgrip, quadriceps, hamstrings, hip abductors, ankles), lower limb explosive power and functional tests (timed up and go, functional reach, timed floor rise and balance), analysed using Linear Mixed Model analysis. Bone Mineral Density (BMD) at hip and spine was measured in a smaller sub-group and analysed using t-tests. **Results:** Significant time*group interactions in all measures of strength, except isometric ankle dorsiflexion, concentric hamstring and eccentric quadriceps strength. These improvements in strength equated to average improvements of 7-45%. There were also significant improvements in explosive power (W/kg) (18%, $p=0.000$), timed up and go (16%, $p=0.000$), functional reach (17%, $p=0.000$), floor rise (10%, $p=0.002$) and eyes closed static balance (56%, $p=0.000$). There was a significant loss of hip BMD in the control group (neck of femur $p<0.05$; ward's triangle $p<0.02$). **Conclusion:** The FaME intervention improves lower limb strength, power and clinically relevant functional outcomes in frequently falling older women.

Keywords: Exercise, Falls, Strength, Power, Bone Health, Physical Function

Introduction

Although the evidence is unequivocal that strength and balance exercise reduces falls in older people^{1,2}, many exercise studies have not shown a reduction in falls even if certain measures of falls risk (such as poor gait, low strength) have been improved¹⁻³. In exercise studies of older adults with better physical function, falls have been reduced without significant changes in physical function^{4,5}.

For a holistic approach to falls prevention in frailer older people, an intervention should not only reduce falls, but also improve strength, power, balance and functional ability if that person is below functionally important thresholds, so that they can remain as active and independent as possible^{6,7}. Indeed, frequent fallers have poor outcomes,

Dawn A. Skelton & Susie Dinan-Young are Directors of Later Life Training Ltd, a not for profit company delivering training (including the Postural Stability Instructor based on FaME) to health and fitness professionals who work with older people to prevent falls. Olga M. Rutherford and Marlene Sandlund have no conflict of interest.

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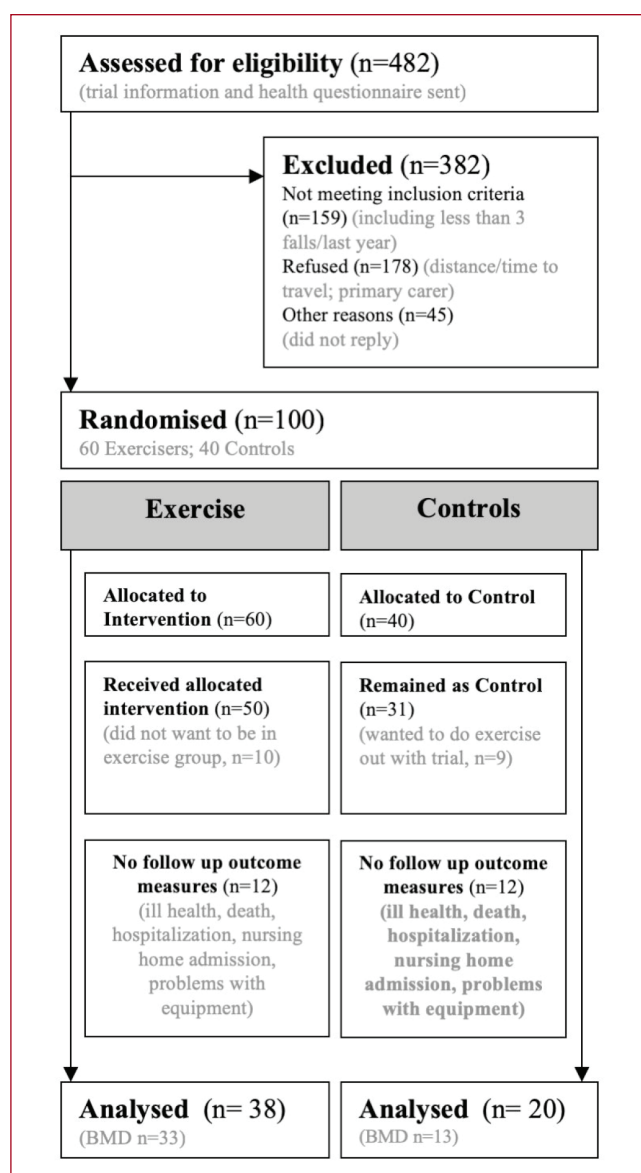


Figure 1. Participant flow in the study.

27% of people who fell three or more times in a year were admitted to hospital, transferred to nursing homes or died at one year follow-up⁸. Poor strength and gait speed are also key indicators for all cause mortality⁹. Falls Management Exercise (FaME), in women with a history of 3 or more falls in the previous year, reduced falls significantly and at follow up, those who had taken part in the FaME exercises were less likely to be in hospital, have entered a nursing home or have died, than those who did not¹⁰. However, the data on changes in muscle strength, power and function, although collected, have not been presented.

Fractures, as an outcome of falls, have debilitating consequences for an individual. Historically, there have

	Exercisers	Controls
Number of women	38	20
Age (years) †	72.0 (5.6)	73.6 (5.8)
Weight (kg) †	65.5 (9.6)	67.2 (9.5)
Height (m) †	1.57 (0.05)	1.58 (0.04)
Number of medications ††	4 (0-9)	4 (0-8)
Walking speed (m.sec ⁻¹)	1.23 (0.24)	1.27 (0.20)
Number using walking aids (canes) (%)	6 (15.8%)	3 (15.0%)

All data as † mean (sd) except †† median (range) and % where indicated.

Table 1. Baseline characteristics of subjects.

been few falls exercise trials which have had fracture as a primary or secondary outcome². However, recently there was a review and meta-analysis that showed exercise had a beneficial effect on reduction of fall-related fractures, with pooled estimates of RR 0.604, alongside improvements in leg strength¹¹. Interestingly, one recent review of long term exercise (≥ 1 year) in older people has also found a significant reduction in fracture¹². Bone mineral density (BMD) is weakly associated with fracture risk¹³, but combined with a history of falls, becomes important in terms of fracture prevention. There has only been one falls exercise trial that has looked at bone mineral density (BMD). This large primary prevention randomised controlled trial of 6 months of FaME in sedentary older people did not find significant changes in BMD in the exercise groups¹⁴. The authors acknowledged that intervention may require a greater magnitude of progressive loading, and/or a longer duration. The original FaME study¹⁰, lasting 9 months and in frailer women, measured BMD but the data has not been published.

FaME is recommended as a cost-effective evidence based programme in the UK, for use in outpatient Hospital and Community based falls prevention teams^{15,16}. Therefore, this paper aims to present the pre- and post- intervention strength, power, functional ability and BMD assessments collected, but not previously reported, in the original FaME Intervention¹⁰.

Materials and methods

Subjects

The participants in this study were community dwelling older women with a history of three or more falls in the previous year, recruited to an RCT of an exercise intervention to reduce falls¹⁰. Inclusion criteria were: female, aged 65 or over, independent living (in their own home without help), a history of three or more falls in the previous year. Exclusion criteria were: acute rheumatoid arthritis, uncontrolled heart

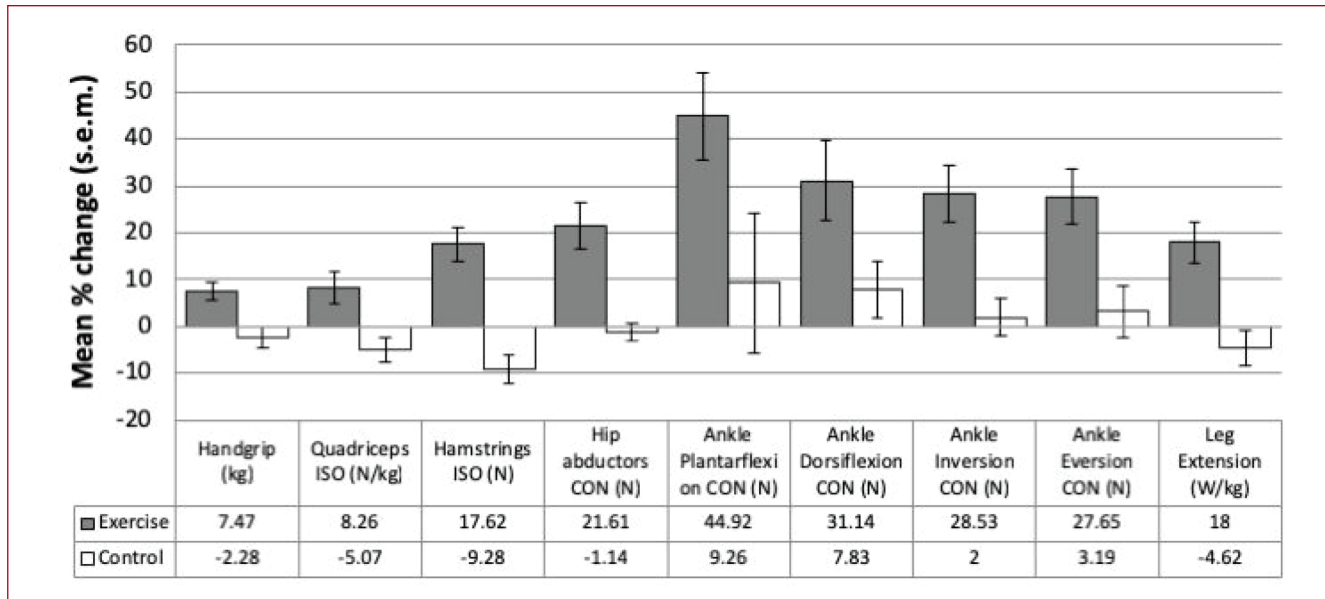


Figure 2. Percentage change in strength and power outcome measures pre-post intervention. (Key: ISO=Isometric; CON=Concentric; N=Newtons; W=Watts; s.e.m=standard error mean).

failure or hypertension, significant cognitive impairment, significant neurological disease or impairment, or previously diagnosed osteoporosis. Further information on ethical approval, written informed consent, study design, recruitment, and randomisation is published (Supplementary Data¹⁰).

Participant flow through the study is presented in Figure 1. Baseline characteristics of the subjects included age, weight, height, number of medications, use of a walking aid and walking speed assessed over a 6m walk (Table 1). Data are presented on the 38 Exercisers and the 20 Controls who completed pre and post intervention strength, power and function assessments. Forty six women (33 exercisers/13 controls) completed BMD pre and post intervention.

Outcome measures

All outcome measures were assessed pre-intervention and post-intervention by the same unblinded researcher.

Strength measurements: Isometric strength of the quadriceps, hamstrings and hip abductors; isokinetic strength (at 100°/sec) of the quadriceps, hamstrings and ankle plantarflexors, dorsiflexors, invertors and evertors, as well as eccentric strength (100°/sec) of the quadriceps was measured using a set protocol¹⁷ on the Kin-Com Isokinetic Dynamometer (Japan). Maximal isometric handgrip strength was measured on a calibrated handgrip dynamometer (Takei Kiki Kogyo, Japan)¹⁸.

Explosive lower limb power was measured on the Nottingham Leg Extensor Power Rig, safe for use in frail older people¹⁹. Maximum power in each leg was recorded

using a set protocol¹⁷. Watts were averaged and divided by the persons body weight to give a functional power measurement (W/kg). Asymmetry in Leg extension power was calculated as the difference between the strongest and the weakest leg divided by the strongest leg.

Functional measures were chosen to be feasible and reliable to use clinically. Functional Reach (FR)²⁰ and Timed Up and Go²¹ (TUG) are valid, clinical markers of balance and functional mobility. Time to rise from side-lying on the floor (Floor rise) was adapted so that the participant could use a hard chair to lean on to support them getting up off the floor²².

Balance was assessed using adapted clinical Romberg tests²³. Each subject stood on one leg (their 'best' leg), eyes open, then after a rest, on one leg with eyes closed. The timer was stopped as soon as they had to put one foot down or be supported (up to a maximum of 30 seconds).

Bone Mineral Density was measured in a non random sample (choice) of participants. BMD of the lumbar spine (L1-L4 and L2-L4) and hip (neck, greater trochanter and Ward's triangle) were measured using dual-energy X-ray absorptiometry (Lunar DPX-L). L2-L4 is reported in addition to L1-L4 as L1 is frequently damaged, or overhung by a rib, in women of this age. Either situation can lead to spuriously high areal BMD values. The coefficient of variation of the technique was between 1-2% in the laboratory used.

Interventions

The Controls were given a set of home exercises (consisting of low intensity seated warm-up, mobility, flexibility and cool-down exercises) to do twice-weekly for

		Exercise		Control		Time*Group interaction LMM
Test		N	Mean (SD)	N	Mean (SD)	
Hand grip (kg)	Pre	38	19.55 (4.72)	20	18.80 (3.37)	F(1, 58)=10.53 p= 0.002
	Post	38	20.71 (4.26)	20	18.38 (3.85)	
Quadriceps isometric (N)	Pre	38	231.80 (63.41)	19	191.61 (51.80)	F(1, 55.52)=7.95 p= 0.007*
	Post	38	244.78 (61.54)	17	186.06 (51.64)	
Quadriceps isometric/kg (N/kg)	Pre	38	3.57(0.95)	19	2.95(0.94)	MW: p<0.008 p= 0.007* MW: p<0.008
	Post	38	3.79(0.93)	17	2.85(0.94)	
Hamstrings isometric (N)	Pre	38	86.72 (26.41)	19	78.55 (20.70)	F(1,55.14)=29.00 p= 0.000
	Post	38	98.53 (22.84)	16	69.84 (20.80)	
Quadriceps concentric (N)	Pre	38	162.07 (56.19)	19	144.47 (41.39)	F(1, 54.56)=4.75 p= 0.034* MW: p<0.01
	Post	38	172.17 (52.26)	16	145.25 (38.31)	
Hamstring concentric (N)	Pre	38	126.93 (43.70)	19	123.21 (27.71)	F(1, 57.08)=0.37 p= 0.544
	Post	38	127.86 (33.40)	16	118.97 (26.06)	
Quadriceps eccentric (N)	Pre	37	335.91 (103.02)	19	287.61 (57.36)	F(1, 53.57)=0.19 p= 0.668
	Post	38	316.13 (100.30)	16	274.19 (71.58)	
Ankle plantar flexion concentric (N)	Pre	37	136.26 (66.41)	18	133.67 (57.87)	F(1,55.96)=10.23 p= 0.002
	Post	37	179.62 (65.66)	17	128.26 (41.63)	
Ankle dorsiflexion concentric (N)	Pre	37	57.05 (17.00)	18	61.53 (15.05)	F(1, 58.63)=1.93 p= 0.170* MW: p=0.06
	Post	37	69.49 (18.29)	16	65.63 (12.89)	
Ankle inversion concentric (N)	Pre	36	66.61 (23.31)	18	59.81 (16.98)	F(1,53.97)=10.39 p= 0.002
	Post	37	80.39 (19.86)	16	62.25 (15.18)	
Ankle eversion concentric (N)	Pre	36	57.39 (18.69)	18	53.06 (13.38)	F(1, 49.81)=4.62 p= 0.036
	Post	35	66.60 (12.65)	16	57.34 (14.55)	
Hip abductor isometric (N)	Pre	37	145.59 (43.51)	18	133.53 (33.79)	F(1, 52.10)=6.27 p= 0.015
	Post	35	171.30 (44.92)	15	137.70 (30.05)	
Leg extension power (W)	Pre	38	89.77 (33.25)	20	87.58(31.64)	F(1,57.08)=13.87 p= 0.000* MW: p<0.01
	Post	37	103.21 (37.09)	20	80.42 (25.13)	
Leg extension power/kg (W/kg)	Pre	38	1.37 (0.47)	20	1.30 (0.48)	F(1, 58)=14.03 p= 0.000* MW: p<0.01
	Post	38	1.56 (0.50)	20	1.18 (0.28)	
Asymmetry Leg extension power (W)	Pre	38	15.68(11.89)	20	16.99(8.20)	F(1, 58)=0.06 p= 0.802
	Post	37	13.04(10.64)	20	15.26(11.53)	

Key: LMM = Linear Mixed Model; N=Newtons; W=Watts; *Residuals skewed, further analysis confirmed significance with Mann Whitney (MW) test.

Table 2. Strength and explosive power pre-post intervention in Exercise and Control Group: Time*Group interaction.

their Intervention. This programme was considered unlikely to improve the components of fitness necessary to maintain postural stability.

The Exercisers attended nine months of FaME classes once a week for an hour, taken by qualified postural stability instructors. The exercise classes were balance specific,

individually-tailored and targeted training for strength, bone health, endurance, flexibility, gait and functional skills training to improve 'righting' or 'correcting' skills to avoid a fall, backward-chaining and floor-work⁷. They also had a set of home exercises (20-40 minutes duration) to perform twice a week.

Data analysis

For the strength, power and functional tests, there was some data missing from some participants on the two occasions (either non attendance or machine failure). Therefore, in order to perform an Intention to Treat (ITT) analysis a linear mixed model (LMM)²⁴ was used. This uses likelihood-based analysis to fit a suitable statistical model to all the observed data. Likelihood-based analyses implicitly assume that the data are missing at random²⁵. A two-level mixed model was applied for each variable with “time (pre-assessment/post-assessment)” and “group” (exercise/control) as fixed factors. The time by group interaction was also included in the models. The intercept for each individual was set as random to create a hierarchical structure with the individual as a level two variable. To verify the robustness of the models the residuals were checked for normality. In cases where skewness or kurtosis were high Mann Whitney tests of pre-post differences between groups were done and all conclusions based on the models were verified.

BMD was measured in a smaller sample who chose to undertake a dual-energy X-ray absorptiometry scan, so paired and unpaired t-tests were used to analyse data within and between groups.

Results

The baseline characteristics (age, weight, height, number of medications, use of walking aid, walking speed) of the participants were not significantly different between groups (Table 1). Walking speed was particularly low in these frequent fallers (average 1.24 m.sec⁻¹). There were no adverse events during the course of the exercise sessions though three women fell, without major injury, on the way to the classes. Of those that remained in the Exercise group, no one attended less than 30 (83%) of the 36 group sessions.

Strength

There were significant time*group interactions seen in isometric handgrip, quadriceps, hamstrings and hip abductor strength (Table 2, and illustrated as mean % change in Figure 2). There were also significant time*group interactions seen in concentric quadriceps, ankle plantarflexion, ankle inversion and ankle eversion strength (Table 2, Figure 2). No significant improvements were seen in isometric ankle dorsiflexion strength, concentric hamstring strength or eccentric quadriceps strength.

Explosive power

There were significant time*group interactions seen in explosive power measurements (both absolute and standardized for body weight for functional relevance) pre- and post-intervention with the Exercisers showing significant and clinically relevant improvements (Table 2 and illustrated as mean % change in Figure 2). There were no significant changes in asymmetry between limbs, either in absolute terms or when standardized to body weight.

Functional measures

There were also significant time*group interactions seen in TUG, FR and Floor rise pre- and post-intervention with the Exercisers showing significant and clinically relevant improvements (Table 3 and illustrated as mean % change in Figure 3).

Balance

There were improvements in eyes closed balance seen in the exercise group in the LMM model, but the skewness of the data suggest that the result is less reliable (Table 3, Figure 3). There was no change in eyes open balance (Table 3 and illustrated as mean % change in Figure 3).

Bone Mineral Density

Baseline characteristics of the 33 Exercisers (E) and 13 Controls (C) in terms of age (E mean 72.1 ± 5.2 years; C mean 70.8 ± 3.7 years), weight (E mean 64.4 ± 9.9 kg; C mean 67.6 ± 10.8 kg) and height (E mean 1.57 ± 0.05 m; C mean 1.58 ± 0.05 m) were not significantly different. The lumbar scan BMD of one subject in the exercise group is not included for data analysis as there was serious damage to all of the vertebra. Hip scans were not conducted on 7 women (3 in exercise group) as there was either difficulty rotating the hip outwards, which is required to get an accurate frontal projection of the hip site, or there was insufficient time to perform the hip scan on both testing occasions.

There was no significant change in BMD in either group for both L1-L4 and L2-L4 (paired t-tests). There was also no significant difference in the % changes following the intervention period between the two groups (unpaired t-test). Absolute BMD values before and after the 9 month intervention period, are given in Table 4 and illustrated as pre-post differences in Figure 4.

The exercise group showed no significant change in BMD at any site in the hip. In the controls there was a significant loss at both the neck (p<0.05) and Ward's Triangle (p<0.02). The difference between the groups was significant at Ward's Triangle (p<0.05). Absolute BMD values before and after the 9 month intervention period, are given in Table 4 and illustrated as pre-post differences in Figure 4.

Discussion

The frequently falling women undertaking this FaME intervention significantly improved their strength, power and functional ability, all known risk factors for falls. These positive changes in muscle and physical function, along with significant reduction in falls rate¹⁰, may have had an important role in the reduced likelihood of a change in residence, hospitalization or death on follow up at 3 years, in these frequently falling older women^{6,10}.

These changes in physical function (TUG, FR) were not seen in ProAct65+, where FaME was examined in lower falls risk sedentary older men and women^{4,5}. Despite being

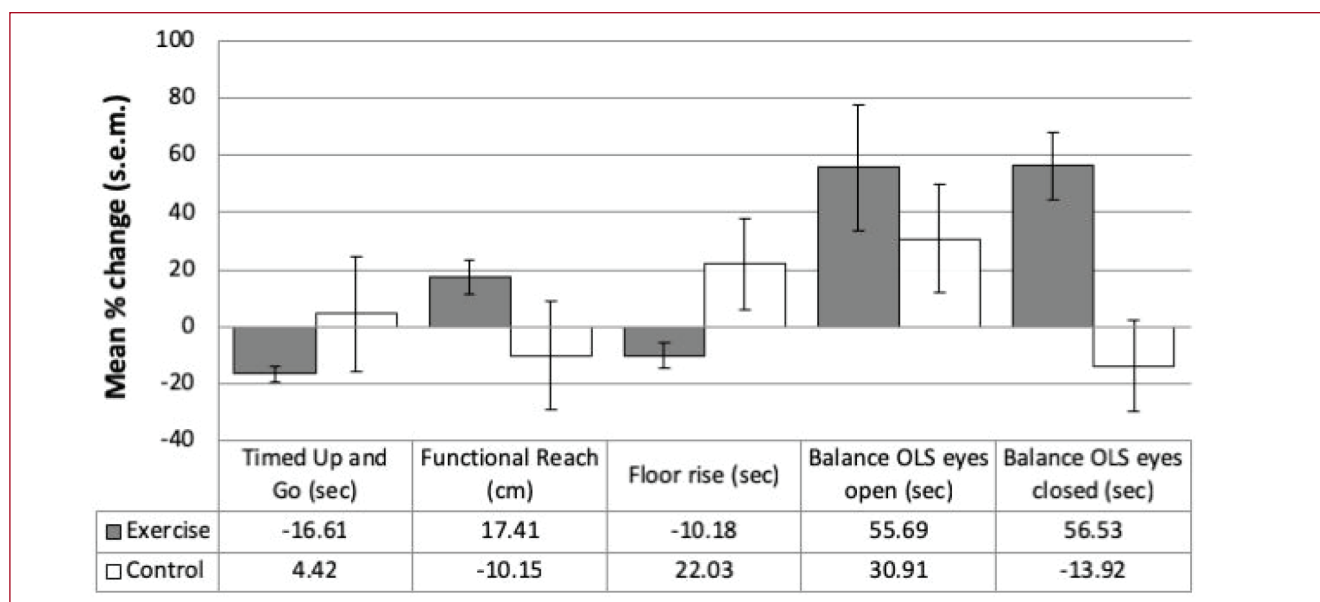


Figure 3. Percentage change in function and balance measures pre-post intervention. (Key: OLS=One Leg Stand; s.e.m=standard error mean)

Test		Exercise		Control		Time*Group interaction LMM
		N	Mean (SD)	N	Mean (SD)	
Timed up-and-go (sec)	Pre	38	9.93 (2.49)	20	10.13 (1.88)	F(1, 58)=18.44 p= 0.000
	Post	38	8.15 (2.31)	20	10.61 (2.75)	
Functional reach (cm)	Pre	38	25.79 (6.38)	19	27.03 (6.18)	F(1, 57)=11.72 p= 0.001
	Post	38	28.42(5.03)	19	24.63 (7.06)	
Floor rise (sec)	Pre	37	8.91 (6.46)	18	9.60 (5.15)	F(1, 55.50)=10.12 p= 0.002* MW: p<0.000
	Post	37	7.29 (4.13)	18	11.18 (5.89)	
Balance eyes closed OLS (sec)	Pre	34	3.28 (2.14)	17	3.39 (2.08)	F(1, 50.62)=14.12 p= 0.000* MW: p<0.000
	Post	36	4.57 (2.87)	16	2.71 (1.14)	
Balance eyes open OLS (sec)	Pre	38	11.77 (8.16)	20	9.97 (6.37)	F(1, 56.48)=0.41 p= 0.522
	Post	37	12.94 (7.89)	19	12.51 (8.60)	
Balance eyes closed/open OLS (sec)	Pre	34	0.32 (0.23)	16	0.33 (0.16)	F(1, 46.60)=4.44 p= 0.040* MW: p<0.004
	Post	36	0.42 (0.22)	16	0.26 (0.13)	

Key: LMM = Linear Mixed Model; OLS=One leg stand. *Residuals skewed, significance confirmed with Mann Whitney (MW) test.

Table 3. Functional ability and balance pre-post intervention in Exercise and Control Group: Time*Group interaction.

based on the same FaME exercises and exercise principles⁷, the population groups in ProAct65+ and the original FaME study were very different. The original FaME study recruited frequently falling older women and ProAct65+ recruited

lower risk men and women who were inactive and had either not fallen or had fallen less than 2 times in the past year. Indeed, the ProAct65+ study population's functional results, when compared with normative data for the general

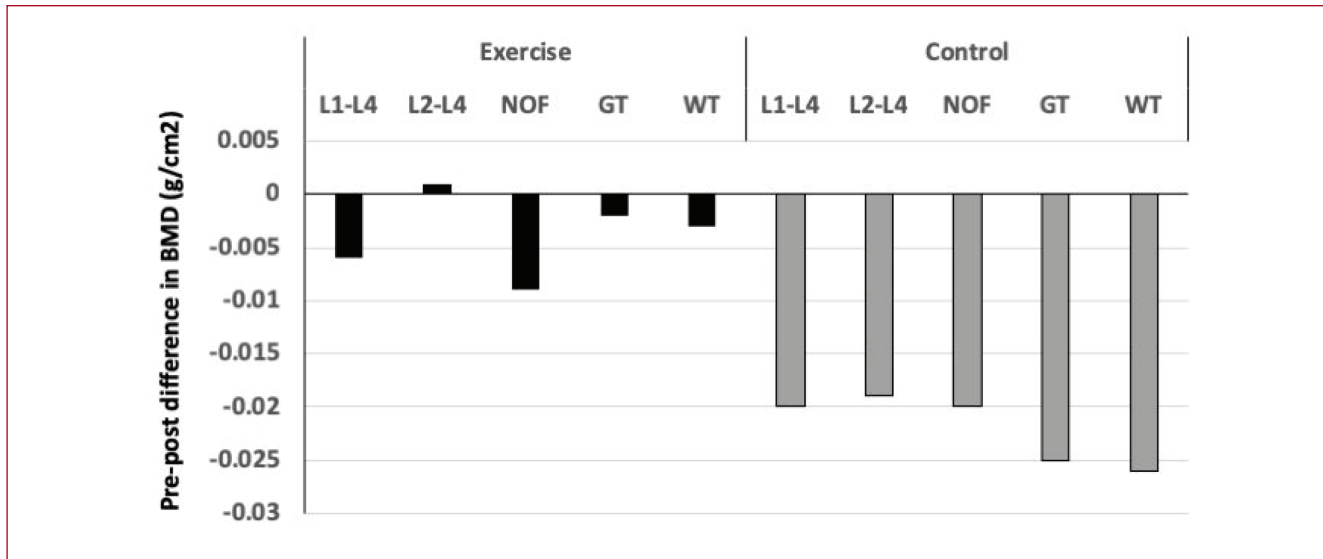


Figure 4. Bone Mineral Density (g/cm²) pre-post intervention differences. (Key: BMD=Bone Mineral Density; L=Lumbar; NOF=Neck of femur; GT=Greater trochanter; WT=Wards Triangle. Difference calculated as post-pre BMD g/cm²).

	Exercise group			Control group		
	n	Pre (g/cm ²)	Post (g/cm ²)	n	Pre (g/cm ²)	Post (g/cm ²)
L1-L4	32	0.984 (0.169)	0.978 (0.159)	13	0.973 (0.138)	0.953 (0.138)
L2-L4	32	1.012 (0.182)	1.013 (0.175)	13	1.003 (0.15)	0.984 (0.146)
Neck of Femur	30	0.783 (0.109)	0.774 (0.104)	9	0.800 (0.079)	0.780 (0.056)
Ward's Triangle	30	0.648 (0.136)	0.645 (0.133)	9	0.726 (0.118)	0.700 (0.115)
Greater Trochanter	30	0.686 (0.106)	0.684 (0.098)	9	0.732 (0.098)	0.707 (0.063)

Values are mean (SD).

Table 4. Bone Mineral Density pre-post intervention in Exercise and Control Groups.

population at baseline, were not particularly poor, suggesting that perhaps there were ceiling effects in these particular functional outcome measures⁵.

So, although FaME reduces the risk of future falls, irrespective of falls risk history, in different populations of risk there are different effects of FaME on muscle, balance and function, suggesting different mechanisms in the prevention of falls with different populations. The FaME intervention also showed a measureable difference in outcomes concerning residential status and mortality¹⁰ in frequently falling women. As this was coupled both with a reduced falls risk and improved muscle strength, it seems tackling sarcopenia and frailty has improved long term outcomes.

The average 18% improvement in functional explosive power (17% in absolute power) in the Exercisers suggests important improvements in ability to maintain independence.

Their mean power rose above the functionally important threshold of 1.5 W/kg, which has been shown to correspond with ability to perform functional tasks²⁶. This suggests an improved chance of using stairs, lifting shopping and getting out of a chair without using arms, all important abilities to retain in order to remain living independently. Despite the home exercise programme having a focus on the weaker limb for each individual (within the home based prescription), as a group there were no significant reductions in asymmetry.

The average 27-45% improvements by the exercise group in ankle plantarflexion, inversion and eversion are gains which will likely improve the participants ability to make the first postural corrections if they trip (ankle strategy) and of course cope with uneven ground. The average 8-21% improvements in quadriceps, hamstring and hip abductor strength will also ensure participants are

more stable and better able to react in the event of a trip. The improvements in isometric quadriceps strength show that the Exercisers strength standardized for body weight rose above the functional threshold of 3.5 N/kg²⁶ to 3.8 N/kg (post-intervention) but the controls saw a decline in quadriceps strength standardized for body weight.

Functional difficulties are common amongst fallers²⁷, for example, their ability to get up off the floor after a fall²⁸. The ability of those who could rise from the floor pre-intervention improved, avoiding the chance of a future long lie. FR improved in the exercise group (17%) but this may not only relate to balance but also potentially they were less fearful of reaching forward post-intervention. There was a reduced ability to reach (~10%) in the control group. TUG, often considered a predictor of falls, also improved (time taken to perform reduced) by nearly 17% in the Exercise group but time increased by 4% in the controls suggesting an increased risk of falls.

The balance tests used in this study were deliberately chosen to be clinically feasible and applicable (30 seconds eyes open and eyes closed single leg stance). Eyes closed balance improved suggesting better integration of sensory balance inputs other than vision. Two of the Exercise group who could not perform the eyes closed balance test prior to the intervention could do post-intervention. The intervention improved the functional tests that are markers of balance (TUG, FR and Floor rise) yet static balance measured using the Romberg test eyes open did not. It maybe that the test itself is not sensitive to change in this particular population, or that dynamic balance was better improved than static balance. Eyes open balance relies heavily on vision and of course the intervention would not have improved this sensory input. Eyes closed balance relies more on proprioceptive feedback from the limbs and it is possible this was impacted on positively by the exercise programme, although we did not measure this parameter.

Whilst not powered on changes in BMD, there were no significant improvements in BMD in the exercise group compared to the control group. However, Figure 4 clearly shows a trend towards the maintenance of bone in the exercise group compared to the loss of bone in the control group. These results, notwithstanding the limitations of an un-blinded assessor and small participant numbers, replicate the results of ProAct65+¹⁴ despite the intervention being a longer duration. Although aspects of exercise known to improve BMD (dynamic aerobic exercise, stepping, progressive strength training) were involved in the FaME sessions⁷, perhaps, due to care with falls risk, the impact was not strenuous enough to have a significant positive effect or indeed a longer duration than 9 months is necessary to show improvements in BMD. However, maintained BMD coupled with a reduced falls risk still had a beneficial effect on injuries and independence at follow up¹⁰.

There are a number of limitations in the evidence from this study. The number of subjects enrolled in the trial

was low compared with those invited but this may be expected as frequent fallers are more likely to be frail and have more medical conditions. Although 60 women were allocated to exercise, only 50 accepted (10 did not want to join intervention when allocated). Another 12, although completing falls diaries, did not complete the follow up strength, power and function tests (24%), as they were unwell (n=3), in hospital (n=2), had moved to a nursing home (n=2), died (n=1), did not want to travel in to do the final tests (n=3) and in one instance there was equipment failure. These individuals are not included in the data analysis and so if tested may have not improved to the same extent as those included in the analysis. This loss to follow up is to some extent expected as they were frequent fallers, who are known to have poor outcomes⁸. Three of the women did not continue in the exercise intervention but their data was still analysed on an intention to treat basis. The BMD measurement was an optional part of the outcomes measures (as already there was considerable burden on the participants) and those that opted to have the measurements may have been more concerned about their bone density. Inevitably, the women in this trial were not blind to their groups and the Exercisers had considerably more contact with members of the trial team (exercise instructors). The researcher recording the outcome measures was aware of the participant group allocation. We have not corrected for potential type 1 errors with our multiple outcomes, primarily as falls was our original primary outcome and this secondary analysis is an exploration of the other effects within these participants. Finally, the muscle and physical function changes seen in these frequent falling women may not be the same in older men as this has not been tested.

This study provides evidence that the FaME intervention supports independent living by improving strength, power and functional ability, as well as significantly reducing risk of falls, lending support to current provision of falls exercise programmes. With a growing focus to help older people reach physical activity guidelines for promotion of health and independence, lower falls risk participants in the ProAct65+ FaME intervention also reported more moderate to vigorous physical activity at 12 months after the intervention, adding around 15 minutes of MVPA per day compared to the usual care group⁵. Unfortunately, changes in physical activity were not assessed in the original FaME intervention. FaME, directed at frequent fallers, was highly effective (IRR 0.69, number needed to treat 5)¹⁰ and if combined with a multifactorial intervention seems likely to provide the greatest benefit to community-dwelling frequent fallers, particularly as it also addresses risk factors, such as strength and power, for functional decline and loss of independence and encourages an increase in habitual physical activity.

Conclusion

The FaME intervention improves lower limb strength, explosive power and clinically relevant functional outcomes.

There is a trend towards better maintenance of hip BMD compared to not exercising. Alongside the reduction in further falls and injuries in high risk (frequent fallers) community dwelling women, and lower risk older men and women in a primary care population, this suggests that the current provision of this intervention in practice in the UK is warranted.

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References

- Sherrington C, Michaleff ZA, Fairhall N, Paul SS, Tiedemann A, Whitney J, Cumming RG, Herbert RD, Close JCT, Lord SR. Exercise to prevent falls in older adults: an updated systematic review and meta-analysis. *Br J Sports Med* 2017;51(24):1750-1758.
- Gillespie LD, Robertson MC, Gillespie WJ, et al. Interventions for preventing falls in older people living in the community. *The Cochrane Database Syst Rev* 2012;9:CD007146.
- Skelton DA, Mavroeidi A. Which strength and balance activities are safe and efficacious for individuals with specific challenges (osteoporosis, vertebral fractures, frailty, dementia)? A Narrative review. *JFSF* 2018;3(2):85-104.
- Gawler S, Skelton DA, Dinan-Young S, Masud T, Morris RW, Griffin M, Kendrick D, Iliffe S for the ProAct65+ team. Reducing Falls among older people in general practice: the ProAct65+ exercise intervention trial. *Arch Gerontol Geriatr* 2016;67:46-54.
- Iliffe S, Kendrick D, Morris R, et al. Multicentre cluster randomised trial comparing a community group exercise programme and home-based exercise with usual care for people aged 65 years and over in primary care. *Health Technol Assess* 2014;18(49):vii-xxvii, 1-105.
- Skelton DA, Mavroeidi A. How do muscle and bone strengthening and balance activities (MBSBA) vary across the life course, and are there particular ages where MBSBA are most important? *JFSF* 2018;3(2):74-84.
- Skelton DA, Dinan SM. Exercise for falls management: Rationale for an exercise programme to reduce postural instability. *Physio Theory Pract* 1999;15:105-20.
- Lord SR, McLean D, Strathers G. Physiological factors associated with injurious falls in older people living in the community. *Gerontol* 1992;38:338-46.
- Hillsdon M, Foster C. What are the health benefits of muscle and bone strengthening and balance activities across life stages and specific health outcomes? *JFSF* 2018;3(2):66-73.
- Skelton DA, Dinan SM, Campbell M, Rutherford O. Tailored group exercise (Falls Management Exercise - FaME) reduces falls in community-dwelling older frequent fallers (an RCT). *Age Ageing* 2005;34(6):636-639.
- Zhao R, Feng F, Wang X. Exercise interventions and prevention of fall-related fractures in older people: a meta-analysis of randomized controlled trials. *Int J Epidemiol* 2017;46(1):149-161.
- de Souto Barreto P, Rolland Y, Vellas B, Maltais M. Association of Long-term Exercise Training With Risk of Falls, Fractures, Hospitalizations, and Mortality in Older Adults: A Systematic Review and Meta-analysis. *JAMA Intern Med* 2018 Dec 28. doi: 10.1001/jamainternmed.2018.5406. [Epub ahead of print].
- Cefalu CA. Is bone mineral density predictive of fracture risk reduction? *Curr Med Res Opin* 2004;20(3):341-9.
- Duckham RL, Masud T, Taylor R, Kendrick D, Carpenter H, Iliffe S, Morris R, Gage H, Skelton DA, Dinan-Young S, Brooke-Wavell K. Randomised controlled trial of the effectiveness of community group and home-based falls prevention exercise programmes on bone health in older people: the ProAct65+ bone study. *Age Ageing* 2015;44(4):573-9.
- Royal College of Physicians. Older people's experiences of therapeutic exercise as part of a falls prevention service - patient and public involvement. London: RCP; 2012. <https://www.rcplondon.ac.uk/projects/outputs/older-peoples-experience-therapeutic-exercise-part-falls-prevention-service> [Accessed 24 Jan 2019]
- Public Health England. Falls and fractures: consensus statement and resources pack. London: PHE; 2017. <https://www.gov.uk/government/publications/falls-and-fractures-consensus-statement> [Accessed 24 Jan 2019].
- Skelton DA, Kennedy J, Rutherford OM. Explosive power and asymmetry in leg muscle function in frequent fallers and non-fallers aged over 65. *Age Ageing* 2002;31:119-25.
- Greig CA, Young A, Skelton DA, Pippet E, Butler FM, Mahmud SM. Exercise studies with elderly volunteers. *Age Ageing* 1994;23(3):185-9.
- Bassey EJ, Short AH. A new method for measuring power output in a single leg extension: feasibility, reliability and validity. *Eur J Appl Physiol* 1990;60:385-90.
- Duncan PW, Weiner DK, Chandler J, Studenski S. Functional Reach: A New Clinical Measure of Balance. *J Gerontol Med Sci* 1990;45(6):M192-7.
- Podsiadlo D, Richardson S. The timed "up & go": a test of basic functional mobility for frail elderly persons. *J Am Geriatr Soc* 1991;39:142-8.
- Skelton DA, Young A, Greig CA, Malbut KE. Effects of resistance training on strength, power and selected functional abilities of women aged 75 and over. *J Am Geriatr Soc* 1995;43:1081-87.
- Iverson BD, Gossman MR, Shaddeau SA, Turner ME Jr. Balance performance, force production, and activity levels in non institutionalized men 60 to 90 years of age. *Phys Ther* 1990;70:348-55.
- Verbeke G, Molenberghs G, editors. *Linear Mixed Models in Practice*. New York: Springer-Verlag; 1997. ISBN: 9781461222941.
- Little RJA, Rubin DB. *Statistical Analysis with Missing Data*. 2nd Edition. Hoboken, New Jersey, USA: Wiley; 2014. ISBN: 9780471183860.
- Skelton DA, Young A, Walker A, Hoinville E. *Physical Activity in Later Life: Further analysis of the Allied Dunbar National Fitness Survey and the HEASAH*. London: Health Education Authority; 1999. ISBN: 0752115731.
- Wolinsky FD, Johnson RJ, Fitzgerald JF. Falling, health status and the use of health services by older adults: a prospective study. *Med Care* 1992;30:587-97.
- Tinetti ME, Lui WL, Claus EB. Predictors and prognosis of inability to get up after falls among older persons. *J Am Med Assoc* 1993;269:65-70.